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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,737	07/09/2001	Edouard G. Lebel	S-21043B	1621
22847	7590	05/19/2005	EXAMINER	
SYNGENTA BIOTECHNOLOGY, INC. PATENT DEPARTMENT 3054 CORNWALLIS ROAD P.O. BOX 12257 RESEARCH TRIANGLE PARK, NC 27709-2257			KUBELIK, ANNE R	
		ART UNIT	PAPER NUMBER	
		1638		
DATE MAILED: 05/19/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/901,737	LEBEL ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Anne R. Kubelik	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 February 2005 and 12 November 2004.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 6-9,13-23 and 30 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 6-9,13-23 and 30 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

Art Unit: 1638

### **DETAILED ACTION**

1. Claims 6-9, 13-23 and 30 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The objection to claim 13 because of an informality is withdrawn in light of Applicant's amendment of the claim.
4. The rejection of claims 6-9, 12-23 and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.
5. The rejection of claims 6-8, 16-19 and 21-23 under 35 U.S.C. 103(a) as being unpatentable over Bennett et al (1992, US Patent 5,168,064) is withdrawn in light of Applicant's amendment of the claims.
6. The rejection of claims 6-8, 12-19, 21-23 and 30 under 35 U.S.C. 103(a) as being unpatentable over Bennett et al (1992, US Patent 5,168,064) in view of Lao et al (1991, J. Bacteriol. 173:3397-3407) is withdrawn in light of Applicant's amendment of the claims.

#### *Claim Objections*

7. Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Parent claim 6 is drawn to a plant transformed with a nucleic acid

Art Unit: 1638

encoding a microbial endoglucanase or endocellulase. As claim 13 is drawn to a plant wherein the endocellulase or endoglucanase is from a microorganism, claim 13 fails to limit the parent claim.

***Claim Rejections - 35 USC § 112***

8. Claims 6-9, 13-23 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.

Claims 6, 13 and 18, line 2, and claim 21, line 1, are indefinite in its recitation of "endocellulase or endoglucanase" in line 2. It is unclear what an endocellulase is and how it differs from an endoglucanase.

9. Claims 6-9, 13-23 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "endocellulase or endoglucanase" in claims 6, 13 and 18, line 2, and claim 21, line

1. The specification does not use the word "endocellulase". It is noted that while the current states of the art includes as endoglucanases only  $\beta$ -1,4-endoglucanases, dependent claim 18 implies that other enzymes called "endoglucanase" are part of the instant invention; however,

Art Unit: 1638

other such enzymes are not supported by the specification. Thus, such a phrase constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

10. Claims 6-9, 13-23 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 6 July 2004, as applied to claims 6-9, 12-23 and 30. Applicant's arguments filed 12 November 2004 have been fully considered but they are not persuasive.

Applicant urges that teaching 20 examples of endoglucanases is sufficient to show those of ordinary skill in the art the invention (response pg 7).

This is not found persuasive because a single fungal  $\beta$ -1,4-endoglucanase coding sequence does not describe a representative number of all fungal  $\beta$ -1,4-endoglucanase coding sequences and only describes  $\beta$ -1,4-endoglucanases from one *Thermomonospora* species, *T. fusca*. However, the *Thermomonospora* genus includes 6 other species, *T. alba*, *T. chromogena*, *T. curvata*, *T. formosensis*, *T. mesophila*, and *T. mesouviformis*; no nucleic acids encoding cellulases are described from any of these species. The specification describes no nucleic acids encoding endocellulases or any endoglucanase other than  $\beta$ -1,4-endoglucanase.

Applicant urges that upon teaching that *T. fusca* encodes a glucanase, it would lead those of ordinary skill in the art to other *Thermomonospora* species for other endoglucanases or endocellulases (response pg 7).

Art Unit: 1638

This is not found persuasive because the structural features of those endoglucanases or endocellulases are not known, and the specification or the prior art must teach them. See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organisms that would encode the protein from that organisms, despite the disclosure of a cDNA encoding the protein from another organism.

11. Claims 6-9, 13-23 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *T. fusca*  $\beta$ -1,4-endoglucanase-encoding sequences and plants transformed with them, does not reasonably provide enablement for nucleic acids encoding all cellulases, plants transformed with those cellulases, or non-transformed plants that express cellulases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 6 July 2004, as applied to claims 6-9, 12-23 and 30. Applicant's arguments filed 12 November 2004 have been fully considered but they are not persuasive.

Applicant urges that the claims do not attempt to claim nucleic acids encoding all cellulases or claim non-transformed plants that express cellulases (response pg 9).

This is not found persuasive because the specification must teach the nucleic acids for plants transformed with those nucleic acids to be enabled.

Art Unit: 1638

Applicant urges that the Office action appears to be repeating the written description requirements (response pg 9).

This is not found persuasive. For the claims to be encoded, the specification must teach microbial endoglucanase and endocellulase coding sequences within the full scope of the claims. The specification teaches no nucleic acids encoding endocellulases or any endoglucanase other than  $\beta$ -1,4-endoglucanase, and of the latter only teaches a single fungal  $\beta$ -1,4-endoglucanase and  $\beta$ -1,4-endoglucanases from only one *Thermomonospora* species. Thus, the claims are not enabled.

Applicant urges that it is not undue experimentation for one of ordinary skill in the art to transform a plant with different endocellulase or endoglucanases once the description explains how to perform such a task with an exemplary endoglucanase (response pg 9).

This is not found persuasive. The rejection is not for plant transformation, *per se*, but for a lack of teaching endoglucanase and endocellulase sequences within the full scope of the claims.

#### ***Claim Rejections - 35 USC § 102***

12. Claims 6-7, 13, 21 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Borri et al (US Patent 5,470,725, filed February, 1990).

Borri et al teach a nucleic acid encoding a thermostable  $\beta$ -(1,3-1,4)-endoglucanase constructed by hybridizing parts of  $\beta$ -glucanase genes from two different *Bacillus* species (column 3, lines 11-24). Borri et al also teach plants transformed with the nucleic acid (claim

Art Unit: 1638

55). Because the plant is capable of expressing the nucleic acid (see parent claim 41), the nucleic acid would be operably linked to a promoter active in plants. It is noted that while the current states of the art includes as endoglucanases only  $\beta$ -1,4-endoglucanases, dependent claim 18 implies that other enzymes called "endoglucanase" are part of the instant invention.

***Claim Rejections - 35 USC § 103***

13. Claims 6-8, 13-26 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ooyen et al (US Patent 5,705,375, filed June 1992) in view of Lao et al (1991, J. Bacteriol. 173:3397-3407).

The claims are drawn to plants transformed with a nucleic acid encoding microbial endoglucanase, including those that are transformed with a nucleic acid encoding endo- $\beta$ -1,4-glucanase from *T. fusca*.

Van Ooyen et al disclose plants and seeds transformed with the *Bacillus licheniformis*  $\alpha$ -amylase gene under control of a constitutive (35S) promoter or an inducible (patatin) promoter (column 11, lines 45, to column 14, line 57). Van Ooyen et al do not disclose plants transformed with a nucleic acid encoding microbial endoglucanase.

Lao et al teach nucleic acids encoding the *T. fusca* E2 and E5 endo- $\beta$ -1,4-glucanases, which are thermostable.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of expressing microbial genes in plants as taught by Van Ooyen et al, to the nucleic acids encoding endo- $\beta$ -1,4-glucanases from *T. fusca* described in Lao et al.

Art Unit: 1638

One of ordinary skill in the art would have been motivated to do so because of the suggestion of Van Ooyen et al to express microbial endo-1,4- $\beta$ -glucanases in plants (column 4, lines 11-36)

14. Claim 9 is free of the prior art given the failure of the prior art to teach or suggest plants transformed with a construct comprising a microbial endoglucanase coding sequence operably linked to a PR-1, PR-1a, PR-2, PR-3, PR-4, or PR-5 promoter. Claim 20 is free of the prior art given the failure of the prior art to teach or suggest plants transformed with a construct comprising nucleic acid encoding a cellulase coding sequence operably linked to vacuole-targeting sequence.

### ***Conclusion***

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

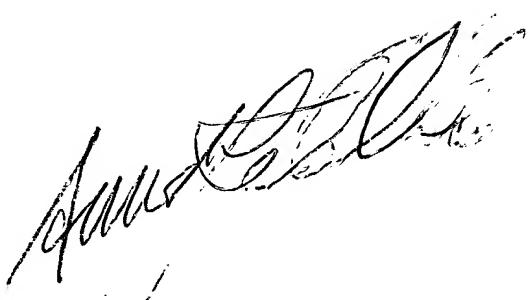
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Art Unit: 1638

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Anne R. Kubelik, Ph.D.  
April 25, 2005



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER